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DATE: May 6, 2004

Please deliver this and the following pages to:

Examiner: **Ardin H. Marschel**
U.S.P.T.O. Group Art Unit: **1631**
Telecopier No.: **571-273-0718**
U.S. Serial No.: **10/083,259**
Client/Matter No.: **ISIS-5423 (formerly PANT-0301)**
Sender's Name: **John A. Harrelson, Jr.**

Pages to Follow: **15**

If transmission is not complete, please call our Philadelphia Office at (215) 568-3100.

Dear Examiner Marschel,

As you discussed with Joe Lucci earlier today, attached hereto are replacement copies of the 3-24-03 Restriction Requirement, the 4-24-03 Response to the Restriction Requirement, and the 7-16-03 Notice. Please let me know if you have any questions.

Respectfully submitted,

A handwritten signature in cursive script that reads 'John A. Harrelson, Jr.'.

John A. Harrelson, Jr.
Reg. No. 42,637

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE INDIVIDUAL OR ENTITY TO WHICH IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL AND EXEMPT FROM DISCLOSURE UNDER APPLICABLE LAW. IF THE READER OF THIS MESSAGE IS NOT THE INTENDED RECIPIENT, OR THE EMPLOYEE OR AGENT RESPONSIBLE FOR DELIVERY OF THE MESSAGE TO THE INTENDED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT ANY DISSEMINATION, DISTRIBUTION OR COPYING OF THIS COMMUNICATION IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, PLEASE NOTIFY US IMMEDIATELY BY TELEPHONE AND RETURN THE ORIGINAL TO US AT THE ABOVE ADDRESS VIA THE U.S. POSTAL SERVICE. THANK YOU.

WOODCOCK WASHBURN LLP
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www.woodcock.com

PHILADELPHIA
One Liberty Place, 46th Floor
Philadelphia, PA 19103
215-568-3100
Fax: 215-568-3439
SEATTLE
999 Third Avenue, Suite 1606
Seattle, WA 98104
206-332-1380
Fax: 206-624-7317

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UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,259	10/19/2001	Peter E. Nielsen	PANT-0301	3290

7390 03/24/2003

Woodcock Washburn LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103

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EXAMINER

MARSCHEL ARDIN H

ART UNIT

PAPER NUMBER

1631

DATE MAILED: 03/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/083,259

Applicant(s)

NIELSEN ET AL.

Examiner

Ardin Marschel

Art Unit

1631

- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-47 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-33, drawn to a modified oligonucleotide or peptide nucleic acid molecule, classified in class 530 and 536, subclasses 300 and 23.1, respectively. If this Group is elected then the below set forth sequence election is also required. Also, if this Group is elected then the below set forth specie election is also required.
- II. Claims 34-39, drawn to a method of treating an infectious disease, classified in class 514, subclass 44. If this Group is elected then the below set forth sequence election is also required. Also, if this Group is elected then the below set forth specie election is also required.
- III. Claims 40 and 41, drawn to a method of identifying a PNA sequence, classified in class 435, subclass 6. If this Group is elected then the below set forth sequence election is also required.
- IV. Claims 42-47, drawn to a method of disinfecting a non-living object, classified in class 435, subclass 262. If this Group is elected then the below set forth sequence election is also required. Also, if this Group is elected then the below set forth specie election is also required.

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Sequence Election Requirement Applicable to All Groups:

Each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group drawn to amino acid sequences, the Applicants must further elect a single amino acid sequence. For an elected Group drawn to nucleotide sequences, the Applicants must elect a single nucleic acid sequence (See MPEP 803.04). Conjugated sequences with certain defined structural features such as set forth in instant claim 21 are selectable to meet this election requirement. It is also noted that an election of an unspecified sequence which are acknowledged embodiments of claim 1, for example, may be elected rather than a specific sequence. It is noted that the multitude of sequence submissions for examination has resulted in an undue search burden if more than one nucleic acid sequence is elected, thus making the previous waiver for up to 10 elected nucleic acid sequences effectively impossible to reasonably implement.

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction requirement and not a specie election requirement.

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Specie Election Requirement Applicable to Groups I, II, and IV:

This application contains claims directed to the following patentably distinct species of the claimed invention:

Specie A: Modified oligonucleotide or PNA composition/method practice without further comprising an antibiotic

Specie B: Modified oligonucleotide or PNA composition/method practice with further comprising an antibiotic

Modified oligonucleotide or PNA practice alone is a broad area of subject matter directed to antisense practice primarily. In contrast mixtures containing an antibiotic also has a broad subject matter set of publications. Thus, these two species are very different in search burden and document the undue search burden if they are searched together.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1, 2, 4-30, and 32 (Group I); 34-39 (Group II); and 42-47 (Group IV) are generic to the above listed species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

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Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The inventions are distinct, each from the other because of the following reasons:

The distinctness between sequences and species has already been set forth above.

Inventions Group I and Groups II - IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the modified oligonucleotide or PNA of Group I may be utilized in the distinct methods of Groups II - IV, or, alternatively, for purification of complementary nucleic acids via hybridization reactions.

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The methods of Groups II – IV are distinct in that they are directed to different subject matter as methods of treatment (Group II), methods of identification (Group III), and methods of disinfecting (Group IV) are clearly distinct usages which are commonly published separately thus documenting the undue search burden if they were searched together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

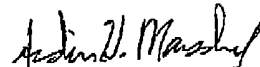
Application/Control Number: 10/083,259
Art Unit: 1631

Page 7

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

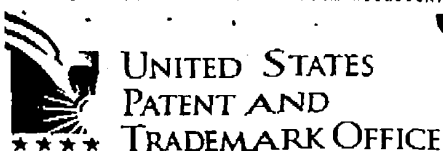
Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

March 21, 2003


ARDIN H. MARSCHEL
PRIMARY EXAMINER

OFFICIAL

MAY 06 2004



FEB 20 2003

Commissioner for Patents
Washington, DC 20231
www.uspto.gov


Dear Patent Business Customer:

The United States Patent and Trademark Office ("Office") is now permitting and encouraging applicants to voluntarily submit amendments in a revised format as set forth in *AMENDMENTS IN A REVISED FORMAT NOW PERMITTED*, Off. Gaz. Pat. Office (February 25, 2003), currently available on the USPTO web site at <http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/revamdtprac.htm>. The revised format permits amendments to the specification and claims to be made in a single marked-up version; the requirement for a clean version is eliminated. Attached, you will find a flyer with information and instructions regarding the procedures to be used to comply with the revised format. The flyers are being inserted with out-going Office actions mailed during the period of February 20, 2003 - March 31, 2003.

The revised amendment format is essentially the same as the amendment format for the specification, claims, and drawings that the Office is considering adopting via a revision to 37 CFR 1.121 (*Manner of Making Amendments*). The revision to 37 CFR 1.121 (if adopted) will simplify amendment submission and improve file management. This proposed revision and others necessary to facilitate a gradual transition to the use of an Electronic File Wrapper (EFW) will be set forth in a Notice of Proposed Rule making (NPR), expected to be published by March 2003. After consideration of public comments, the Office anticipates adopting a revision to § 1.121, following publication of a Notice of Final Rule making (NFR), expected by June 2003, at which point compliance with revised § 1.121 will be mandatory.

The Office will continue to accept your amendment submissions in the revised format during the voluntary period, which will extend up to the effective date of final revisions to § 1.121. The Office also encourages your feedback on the proposed revised amendment format and other changes set forth in the NPR, expected to be published by March 2003.

For assistance: Any questions regarding the submission of amendments pursuant to the revised practice should be directed to Office of Patent Legal Administration (OPLA), Legal Advisors Elizabeth Dougherty (Elizabeth.Dougherty@uspto.gov), Gena Jones (Eugenia.Jones@uspto.gov) or Joe Narcavage (Joseph.Narcavage@uspto.gov). Alternately, you may send e-mail to "Patent Practice", the OPLA e-mail address that has been established for receiving queries and questions about patent practice and procedures or telephone OPLA at (703) 305-1616.


Nicholas P. Godici
Commissioner for Patents

Attachment: Flyer entitled: *Revised Notice* AMENDMENTS MAY NOW BE SUBMITTED IN REVISED FORMAT*

AMENDMENTS MAY NOW BE SUBMITTED IN REVISED FORMAT

The United States Patent and Trademark Office (USPTO) is permitting applicants to submit amendments in a revised format as set forth below. Further details of this practice are described in *AMENDMENTS IN A REVISED FORMAT NOW PERMITTED*, signed January 31, 2003, expected to be published in *Official Gazette* on February 25, 2003 (Notice posted on the Office's web site at

<http://www.uspto.gov/web/offices/pac/dapp/opia/preognotice/revamdtprac.htm>). The revised amendment format is essentially the same as the amendment format that the Office is considering adopting via a revision to 37 CFR 1.121 (Manner of Making Amendments). The revision to 37 CFR 1.121 (if adopted) will simplify amendment submission and improve file management. The Office plans to adopt such a revision to 37 CFR 1.121 by July of 2003, at which point compliance with revised 37 CFR 1.121 will be mandatory.

Effective immediately, **all** applicants may submit amendments in reply to Office actions using the following format. Participants in the Office's electronic file wrapper prototype¹ receiving earlier notices of the revised practice may also employ the procedures set out below.

REVISED FORMAT OF AMENDMENTS**Begin on separate sheets:**

Each section of an Amendment (e.g., Claim Amendments, Specification Amendments, Drawing Amendments, and Remarks) should begin on a separate sheet. *For example*, in an amendment containing a.) introductory comments, b.) amendments to the claims, c.) amendments to the specification, and d.) remarks, each of these sections must begin on a separate sheet. This will facilitate the process of separately indexing and scanning of each part of an amendment document for placement in an electronic file wrapper.

Two versions of amended part(s) no longer required:

The current requirement in 37 CFR 1.121(b) and (c) to provide two versions (a clean version and a marked up version) of each replacement paragraph, section or claim will be waived where an amendment is submitted in revised format below. The requirements for substitute specifications under 37 CFR 1.125 will be retained.

A) Amendments to the claims:

Each amendment document that includes a change to an existing claim, or submission of a new claim, **must include a complete listing of all claims in the application**. After each claim number, the status must be indicated in a parenthetical expression, and the text of each claim under examination (with markings to show current changes) must be presented. The listing will serve to replace all prior versions of the claims in the application.

- (1) The current status of all of the claims in the application, including any previously canceled or withdrawn claims, must be given. Status is indicated in a parenthetical expression following the claim number by one of the following: (original), (currently amended), (previously amended), (canceled), (withdrawn), (new), (previously added), (reinstated - formerly claim #_), (previously reinstated), (re-presented - formerly dependent claim #_), or (previously re-presented). The text of all pending claims under examination must be submitted each time any claim is amended. Canceled and withdrawn claims should be indicated by only the claim number and status.
- (2) All claims being currently amended must be presented with markings to indicate the changes that have been made relative to the immediate prior version. The changes in any amended claim should be shown by strikethrough (for deleted matter) or underlining (for added matter). An accompanying clean version is not required and should not be presented. Only claims of the status "currently amended" will include markings.
- (3) The text of pending claims not being amended must be presented in clean version, i.e., without any markings. Any claim text presented in clean version will constitute an assertion that it has not been changed relative to the immediate prior version.

¹ The Office's Electronic File Wrapper prototype program is described in *USPTO ANNOUNCES PROTOTYPE OF IMAGE PROCESSING*, 1265 *Off. Gaz. Pat. Office* 87 (Dec. 17, 2002) ("Prototype Announcement"), and applies only to Art Units 1634, 2827 and 2834.

Flyer for mailing with all Office actions by all TCs (except Art Units 1634, 2827 and 2834)
02/13/03

DOCKET NO.: PANT-0301

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Confirmation No.: 3290

Peter E. Nielsen et al.

Serial No.: 10/083,259

Group Art Unit: 1631

Filing Date: October 19, 2001

Examiner: Ardin H. Marschel

For: Modified Peptide Nucleic Acid (PNA) Molecules

EXPRESS MAIL LABEL NO: EV 160094127 US
DATE OF DEPOSIT: April 24, 2003

Assistant Commissioner for Patents
Washington DC 20231

Sir:

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REPLY

OFFICIAL

This is in response to the Official Action dated March 24, 2003.

AMENDMENT

In the claims:

Please cancel claims 1-4, 21, 29, and 34-47.

REMARKS

Claims 5-20, 22-28, and 30-33 are pending. Applicants elect Group I for examination. Applicants note that in our October 19, 2001 Patent Application Transmittal Letter, it was asked that claims 1-4, 21, 29, and 34-47 be canceled. That request is resubmitted at this time.

DOCKET NO.: PANT-0301

- 2 -

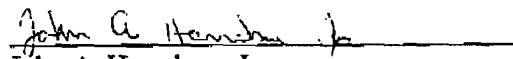
PATENT

The Office Action further requires election of a species for examination. Applicants elect the species of Seq. ID No. 35. Claims 5-7, 10-17, 19, 22-28, and 30 read on the elected species. The selection of species is being made to aid the Examiner in conducting a search and examination of the claimed subject matter, and is not to be construed as limiting the scope of Applicant's claims. It is also Applicant's understanding that if the elected subject matter is found to be allowable over the prior art, the search and examination will be expanded to cover other species, until it includes the full scope of the generic claims.

Applicants believe that the foregoing constitutes a complete and full response to the Office Action of record. Accordingly, an early allowance of all of pending claims is earnestly solicited.

Attached hereto is a marked-up version of the changes made to the claims by the present amendment. The attached page is captioned "Version With Markings To Show Changes Made".

Date: April 24, 2003


John A. Harrelson, Jr.
Registration No. 42,637

Woodcock Washburn LLP
One Liberty Place - 46th Floor
Philadelphia PA 19103
Telephone: (215) 568-3100
Facsimile: (215) 568-3439

DOCKET NO.: PANT-0301

- 3 -

PATENT

VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the claims:

Please cancel claims 1-4, 21, 29, and 34-47.



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/083,259	10/19/2001	Peter E. Nielsen	PANT-0301	3290

7590 07/16/2003
Woodcock Washburn LLP
One Liberty Place - 46th Floor
Philadelphia, PA 19103

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JUL 21 2003

Woodcock Washburn

EXAMINER	
MARSCHIEL, ARDIN H	
ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 07/16/2003

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JUL 25 2003
Kathy Kenney
Woodcock Washburn



UNITED STATES DEPARTMENT OF COMMERCE
U.S. Patent and Trademark Office
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Alexandria, Virginia 22313-1450

APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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EXAMINER

ART UNIT

PAPER

10

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner for Patents

The communication, filed on 4/24/03, is non-responsive to the prior Office action, mailed 3/24/03, because there was no indication therein of a specie election corresponding to the required specie election as set forth on pages 4-5 of said Office action, mailed 3/24/03. Since the response appears to be bona fide, but through an apparent oversight or inadvertence failed to provide a complete response, applicant is required to complete the response within a time limit of one month from the date of this letter or as extended as follows. **AN EXTENSION OF THIS TIME LIMIT MAY BE GRANTED UNDER EITHER 37 C.F.R. ' 1.136(a) OR (b) UP TO A MAXIMUM OF SIX MONTHS.**

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

The CM1 Fax Center number is either (703)305-3014 or (703)308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached at (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703)308-0196.

July 11, 2003
10/083,259

Ardin H. Marschel
ARDIN H. MARSCHEL
PRIMARY EXAMINER

PTO-90C (Rev.04-03)